DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

Ref: 97-DAL-WL-28

June 23, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Steve Morgan, Owner
Texas Show Supply
Route 1, Box 152
Barry, Texas 75102

Dear Mr. Morgan:

An investigation of your veterinary products sales facility located at Route 1, Box 152, Barry, Texas 75102, conducted by the U.S. Food and Drug Administration (FDA) on May 5 and 14, 1997, revealed the sale and promotion of a veterinary drug, "JUST WIN", which is adulterated within the meaning of Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act). The product is also misbranded within the meaning of Section 502(f)(1) of the Act.

Our investigation determined that you provided labeling in the form of a "JUST WIN PRODUCT INFO" sheet bearing the following claims:

- "Provides important nutrients to increase hair growth."
- "Stimulates appetite"
- "Increase bulk of muscles"
- "Key is sarparilla (sic) which produces testerone (sic) and progesterone."
- "Sarsaparilla stimulates pituatary (sic) gland. (Hormones are part of Sarsaparilla)."
- "Sarsparilla (sic) has a calming effect"

Under Section 201(g)(1) of the Act, a "drug" is defined, in part, as any article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal, or intended to affect the structure or function of man or other animal. Because of the claims promoted on the labeling and the product's intended use, "JUST WIN", meets this definition.

The drug is adulterated under Section 501(a)(5) in that it is a new animal drug, as defined in Section 201(w) of the Act, which is unsafe within the meaning of Section 512. Section 201(w) defines a new animal drug as one, the composition of which is such that the drug is not generally recognized among qualified experts as safe and effective for use, under the conditions prescribed, recommended or suggested in the product's labeling. Section 512, in part, deems a new animal drug unsafe unless it is the subject of an approved New Animal Drug Application (NADA). NADA's may be approved on the basis of adequate scientific data which the applicant submits as evidence of the safety and effectiveness of the product.

The drug is also misbranded under Section 502(f)(1) of the Act. A drug is misbranded unless its labeling bears adequate directions for its intended use. Since the safety and effectiveness of the drug has not been established, adequate directions for its intended use cannot be written.

The above is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that your overall operation and the products you label, promote, and distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including explanations of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed. Also include any available documentation demonstrating that corrections have been made.

Your response should be directed to Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely yours,

Joseph R. Baca
Dallas District Director

JRB:RRR